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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/290,798	04/13/1999	INGEGERG HELLSTROM	9632-033	1277

20583 7590 03/09/2005

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT PAPER NUMBER

1642

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/290,798	Applicant(s) HELLSTROM ET AL.	
	Examiner Christopher H. Yaen	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 101, 102, 104-106, 109-116 and 120-127 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 101, 102, 104-106, 109-116 and 120-127 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Re: Hellstrom et al
Priority Date: 30 June 189

1. The amendment filed 11/19/2005 is acknowledged and entered into the record. Accordingly, claims 1-100, 103, 107-108, 117-119, and 128 are canceled without prejudice or disclaimer.
2. Claims 101-102, 104-106, 109-116, and 120-127 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

4. The rejection of claims 101-102, 104-106, 109-116, and 120-127 are under 35 USC § 103(a) as being obvious over Abe *et al* (Cancer Res. 1986 May; 46:2639-2644) in view of Oldham *et al* (J. Biol. Resp. Modifiers 1983;2:1-37) and Sahagan *et al* (J. Immunol 1986;137:1066-1074) is maintained for the reasons of record. Applicant argues that the cited references do not provide sufficient suggestion or motivation to modify either alone or in combination and thus a *prima facie* case of obviousness has not been established.

More specifically, applicant indicates that Abe *et al* provides no motivation that would suggest an immunoconjugate that comprises an antibody joined to a therapeutic agent and could only be viewed as an antibody that has "*prognostic value* for colonic polyps" (see page 5 of response). Applicant concludes that Abe *et al* discloses an AH6

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antibody that be have diagnostic and not therapeutic value. Applicant additionally contends that Oldham *et al* fails to satisfy the deficiencies of Abe *et al* and specifically points to non-enabling aspects of the cited reference. Finally, applicant argues that Sahagan *et al* do not satisfy the deficiencies of either Abe *et al* or Oldham *et al* because Sahagan *et al* do not discuss immunoconjugates. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The claims of the instant invention are drawn to an immunoconjugate "joined" to a therapeutic agent. Subsequent claims (i.e. claim 109) further define the therapeutic agent as a second antibody. Moreover, the specification has defined an immunoconjugate as any molecule that is chemically or biologically linked to a therapeutic agent (see page 27, lines 1-10). In addition, the term therapeutic agent has not been limited to any specific types of "agent" and is indicated in the specification as including "any agent useful for therapy". Abe *et al* teaches an AH6 antibody that is specific for a Lewis Y carbohydrate antigen of which that has been complexed with a secondary antibody (see page 2639, 2nd col.). Abe *et al* indicate that this antibody-second antibody complex was able to localize the antibody to specific regions of a tumor tissue (see figure 2, page 2641). This "immunoconjugate" has thus been proven to be useful for the localization and detection of an antigen on a tumor cell. Oldham *et al* clearly indicates that antibodies are useful for treatment in cancer because they are able to target structures on a cancer and enable the antibody itself to be therapeutic or when conjugated to a drug or toxin, enables the antibody to act as a targeting agent. Although Oldham *et al* do indicate, as stated by the applicant, that there be additional

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studies with immunoconjugates performed, the conjugation of an antibody to a therapeutic agent was proven effective and capable of reducing tumor burden (see page 20, lines 15-18). Thus one of ordinary skill in the art would find motivation because

- a. Abe *et al* taught an antibody that is capable of competitively inhibiting the binding of a BR96 antibody, an antibody that was able to specifically target a tumor specific antigen (i.e. Lewis Y antigen) on a tumor cell, and a complex or immunoconjugate of the AH6 antibody; and
- b. Oldham *et al* taught that antibodies to tumor specific antigens "can be conjugated with a variety of toxic agents and administered either in vivo or used in vitro for therapeutic effect" (see page 22).

One of skill in the art would have found sufficient motivation and a reasonable expectation of success because Abe *et al* taught a tumor targeting antibody as well as an immunoconjugate, Oldham *et al* taught that any antibody so long as it targets a tumor specific antigen can be conjugated to a toxic agent and further showed effectiveness of an antibody conjugated to a toxin to reduce tumor burden. Thus reasonable motivation was provided in both these references.

Both Abe *et al* and Oldham *et al* do not specifically teach the addition of a human Fc to the immunoconjugates, this is obvious because the immunoconjugate was intended for the administration to a human subject, and therefore, to circumvent adverse reactions such as HAMA in a human the addition of a human Fc region would

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be obvious in view of the teachings provide by Sahgan *et al.* Therefore, the rejection of the claims under 35 USC 103(a) as being obvious is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
March 2, 2005


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER

3/5/05